

Serial No.: 10/532,716
Atty. Docket No.: P70568US0

REMARKS

The Office Action mailed October 8, 2008, has been carefully reviewed and, to facilitate prosecution, Applicant requested a personal interview which was conducted by Examiner Anderson on February 5, 2009. Applicant was represented by Suzin Bailey. Applicant sincerely thanks Examiner Anderson for her time and cordiality in conducting the interview.

During the interview, the prior art patents to Holmberg (U.S. Patent No. 5,496,296) and Steer (U.S. Patent No. 4,890,608) were discussed, and Applicant presented a product sample of an ostomy device having a base plate with a first flange and a collecting bag with a second flange, the second flange referred to hereinafter as "the bag flange", in accordance with the claimed invention. The structural features of the bag flange, including the flexible layer and adhesive layer bonded thereto as demonstrated, were discussed in contrast with the disclosure of Steer which is directed to the flange on the base plate, i.e., the "first flange" in the present invention.

Now responding to the Office Action mailed October 8, 2008, by this Amendment, Applicant has canceled claims 2, 5 and 11, amended claims 1, 7, 9, 12, 14, 15 and 19, and added claims 20-24.

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Claims 1, 3, 4, 6-9 and 12-24 are pending in the application.

Claims 1, 9 and 14 are independent.

The Examiner rejected claims 1-9 and 11-19 under 35 U.S.C. 103(a) as being unpatentable over Holmberg in view of Steer.

As amended herein, claim 1 is directed to an ostomy device including a body side member and a collecting bag including a coupling element. The body side member includes a base plate for adherence to the skin of a user and a body side flange configured for repeated and removable adhesive connection to the coupling element. The coupling element includes a bag flange made of a material that has a different tensile strength than that of the material from which the body side flange is made, and an adhesive layer to achieve the removable adhesive connection with the body side flange.

Given that the body side flange is configured for repeated and removable adhesive connection to the coupling element, the body side member and the collecting bag are subject to repeated stresses as they are separated from one another. The flange having the lower tensile strength, i.e., "the softer flange", is designed to provide flexibility to ensure a good seal but, to do so, may have a lower tensile strength than the adhesive. This can result in residues of the softer flange material being left on the

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counterpart coupling member upon separation of the collecting bag from the body side member (see page 2, lines 11-19). Such residue must then be removed before a new collecting bag can be connected to the body side member.

In order to ensure that the softer flange remains intact, a flexible layer having a yield strength exceeding the adhesive strength of the adhesive layer is bonded to the outer surface of the softer flange. The adhesive layer providing the adhesive connection between the body side flange and the coupling element is then affixed to the outer surface of this flexible layer. This formation of a layered structure composed of the softer flange, the flexible layer and the adhesive layer, is not shown by the prior art.

Holmberg is directed to an ostomy appliance with an adhesive faceplate for attachment to the user, the faceplate 12 having a stoma-receiving opening therein through which the stoma projects. To protect the skin around the stoma from exposure to stomal fluids, a soft sealing material 31 made of a skin-friendly, tacky, hydrocolloid-containing, moisture-absorbing skin barrier material is placed around the stoma-receiving opening to form a fluid-resistant gasket around the stoma, protecting the peristomal skin surfaces (see the abstract). Hence, Holmberg is directed to

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a different problem than that being solved by the present invention. And, as correctly noted by the Examiner, Holmberg does not disclose a flexible layer between the flange having the lower tensile strength and the layer of adhesive that connects the bag coupling element with the body side flange as set forth in claim 1. Accordingly, the Examiner has relied upon Steer for this teaching.

Steer is directed to an attachment assembly in the form of a body side member 10 for being affixed to a user's skin and having a plurality of adhesive layers 34 thereon which may be separated from one another by a corresponding number of release papers. The body side member has a flange 20 with a central opening which is placed over a wound, and each adhesive layer is then used individually, one at a time, to connect a respective article such as a wound covering 12, also replaced one at a time, to the body side member. Each time a wound covering is removed, the existing adhesive layer that held the wound covering is also removed, exposing a fresh adhesive layer to affix the next new wound covering. In this way, the same body side member can remain in place on the user while the wound covering is replaced a number of times corresponding with the number of adhesive layers on the body side member.

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Steer is silent, however, with respect to the relative tensile strengths of the body side flange 20 and the flange 16 on the wound covering 12. Steer also does not disclose a flexible layer affixed to the "softer" flange or that this flexible layer is positioned between the "softer" flange and the layer of adhesive that connects the wound covering with the body side adhesive layer. Steer also does not disclose that the bond between the outer surface of the softer flange and the flexible layer is stronger than the adhesive connection between the body side flange and the wound covering flange. In fact, none of these comparisons even make sense when viewing Steer because Steer lacks the claimed flexible layer and, because Steer is directed to an entirely different problem than that being addressed by the present invention, Steer has no need for the claimed flexible layer. Since Holmberg also lacks a flexible layer, and since no one of skill in the art would find either Holmberg or Steer pertinent to the problem of how to keep a low tensile strength flange intact while not sacrificing the flange's flexibility, claim 1 is patentable over Holmberg in view of Steer.

Claims 9 and 14 are also in condition for allowance for the same reasons as claim 1 and further as specifying that the "softer" flange is *on the collecting bag*. When comparing Steer

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with the present invention, the wound covering 12 of Steer is the element that corresponds with the collecting bag as claimed. Steer, however, is directed to the body side member 10 and says *nothing* about the nature and characteristics of the wound covering 12. Hence, it would be pure conjecture to speculate that the wound covering has a "softer" flange than the body side member or that the wound covering has a flexible layer bonded on its outer surface to which an adhesive layer is affixed as set forth in each of claims 9 and 14. And in fact, there is no support for such conjecture since Steer lacks any requirement for a flexible layer designed to protect the integrity of the underlying wound covering flange since, according to Steer, when the wound covering 12 and flange 16 are removed, the respective adhesive layer that was used to hold the wound covering is also removed. Therefore, it would be immaterial whether the "softer" flange of the wound covering left any residue on the body side adhesive layer as both are disposed of together.

For at least the foregoing reasons, claims 1, 9 and 14 are patentable over the prior art. Favorable reconsideration and allowance thereof, along with claims 3, 4, 6-8, 12, 13 and 15-24 dependent thereon, is requested.

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More particularly with respect to the new and amended dependent claims, the prior art does not disclose that the softer flange is made of a foam material as set forth in claims 7, 21 and 23, or that the flexible layer is a film bonded to the softer flange as provided in claims 19, 20 and 22-24.

With this amendment and the foregoing remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any questions or comments, the Examiner is cordially invited to telephone the undersigned attorney so that the present application can receive an early Notice of Allowance.

Respectfully submitted,

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